REMARKS

This paper is being filed with a Request for Continued Examination. The amendments and comments appearing herein are responsive to an *Official Action* that issued in this case on June 29, 2007.

In that *Action*, the Examiner rejected claims 1 and 2 under 35 USC §112, ¶2. Furthermore, the Examiner finally rejected claims 1, 3, 5, 10-16, and 20-28 under 35 USC §102 as being anticipated by U.S. Pat. No. 6,470,302. All other claims were rejected under 35 USC §103 as being obvious over the '302 patent either alone or in combination with other references.

Responsive to the rejection, claim 1-4, 6, 10, and 12 have been amended and claims 7, 9, and 11 have been canceled. Reconsideration is requested in view of the foregoing amendments and the following comments.

Rejections Under 35 USC §112, ¶2

The Examiner alleges that:

> Claim 1 is unclear and indefinite as to how "a feature of said needle and a feature of said catheter can be relative to an axis aligned with a length of said needle or said catheter if they are not one in the same."
>
> Claim 2 is rejected for lack of antecedent basis because the phrase "said feature" is "unclear as to which said feature and how many of said features." Furthermore, claim 2 is further rejected as unclear and indefinite as "to what feature or features creates a bevel."

Claim 1, as amended, recites:

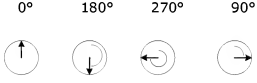
> a needle;
> a catheter, wherein said catheter receives said needle;
> a sensor, wherein said sensor senses an angle of rotation of at least one of said needle and said catheter about a roll axis that is aligned with a length of said needle; and
> pseudo skin, wherein said pseudo skin comprises an opening for receiving said needle and said catheter.

The subject matter of claim 1 is a needle/catheter module. It is representative of a needle/catheter that a medical practitioner would insert into a patient's arm, *etc.*, during a vascular access procedure. *See*, FIGs. 5-7.

It should be clear from FIG. 5 that when the needle portion and catheter portion are coupled to one another, they are co-axial. It is also noted at paragraph [0069] that the needle portion 536 and the catheter portion 554 are configured for locking engagement, such as by inserting ridge 644 into a complementary slot in coupler 756 of catheter 554.

Unlike the cited art, the needle/catheter module that is recited in claim 1 is capable of sensing its angle of rotation about its long (*i.e.*, roll) axis. The significance of this ability to sense angular orientation is explained at paragraph [0054].

The angle being sensed is illustrated by the drawings below. The needle/catheter assembly is assumed to be pointing "into" this page. The "roll axis" aligns with the long axis of the assembly, so that it, too, is pointing into the page. In the figures below, the "circle" represents the full possible 360° of rotation about the roll axis. The arrow is meant to indicate a point on the needle/catheter assembly. The four figures below depicts various amounts of rotation about the roll axis, depicting, respectively, a 0°, 180°, 270°, and 90° angle of rotation.



Any issues surrounding use of the term "feature" are now moot, since that language has dropped from claim 1. Also, the claim now recites that the axis is a "roll axis" that is aligned with a length of the needle. That is intended to clear up any ambiguity about precisely which axis is being referenced in the claim. Since the needle and the catheter are co-axial, the referenced axis is, by definition, also aligned with the length of the catheter. Referencing only the needle (as opposed to both the needle and the catheter) improves the readability of the claim. It is notable that the claim could recite "aligned with a length of the catheter" and it would have the same meaning. It is believed that the amendment to claim 1 will overcome the Section 112 rejection.

Rejection of Claim 1
Under 35 U.S.C. 102
Over Cunningham

Amended Claim 1 recites an apparatus comprising:

> a needle;
> a catheter, wherein said catheter receives said needle;
> a sensor, wherein said sensor senses an angle of rotation of at least one of said needle or said catheter about a roll axis that is aligned with a length of said needle; and
> pseudo skin, wherein said pseudo skin comprises an opening for receiving said needle and said catheter.

Claim 1 has been amended to delete reference to a "feature," to clarify the specific "angle" being sensed, and to add a limitation concerning "pseudo skin."

Cunningham does not disclose what is recited in claim 1. Namely, Cunningham does not disclose sensing the angular orientation of a needle or catheter about a roll axis thereof.

As disclosed at col. 9, lines 21+, the various degrees of freedom of the Cunningham devices include the "pitch" of catheter needle assembly, which is provided by the axis of rotation of bearing (42), the "yaw" of the catheter needle assembly, which is provided by the axis of rotation of bearing (58), and "translation" of the catheter needle assembly, which is provided by translation of shaft (44). (See, Figure 4.) Clearly, it would not be possible, using Cunningham's design, to sense the particular angle referenced in claim 1.

Cunningham mentions a computer interface device having a pen-like stylus supported on a linkage having six degrees of freedom. Cunningham, however, distinguishes this device, as not resembling a medical instrument and not having the ability to provide force feedback, thereby degrading it's realism. It should be noted that the owner of the Cunningham patent, Immersion Medical, is also the owner of the six-degrees of freedom computer interface device. Yet, even with initimate knowledge of this device, Cunningham could not produce a simulator having a needle/catheter that could sense it's own angle of rotation. There is no comparison, mechanically, between a pen-like device having multiple degrees of freedom of movement and that doesn't couple to anything, on the one hand, and devices like Cunningham's or applicants' wherein there is a needle/catheter that actually physically interfaces with mechanisms, *etc.*, or penentrates a surface to simulate vascular access.

Claim 1 now recites a "pseudo skin" having an opening that receives the needle/catheter. This feature is not disclosed Cunningham.

As a consequence, claim 1 is allowable over the cited art. Claims 2 through 11 are allowable based on their dependence on claim 1. Furthermore, the recitation of additional patentable features in these claims provides a secondary basis for their patentability.

Rejection of Claim 12
Under 35 U.S.C. 102
Over Cunningham

Amended claim 12 recites:

> pseudo skin;
>
> a force-feedback assembly, wherein said force-feedback assembly is disposed beneath and at least partially covered by said pseudo skin; and
>
> an end effector, wherein said end effector passes through said pseudo skin to reversibly couple to said force-feedback assembly.

Cunningham does not disclose or suggest what is recited in claim 12. Namely:

1. In Cunningham, the force-feedback assembly is not disposed beneath and at least partially covered by the pseudo skin.
2. In Cunningham, the end effector does not pass through the pseudo skin (belt 108).
3. In Cunningham, the end effector does not reversibly couple to the force feedback mechanism.

Regarding point no. 1, in Cunningham, the "pseudo skin" — belt (108)— is disposed in skin traction mechanism (36). Cunningham's force-feedback unit (54), however, is positioned below catheter needle assembly (47) and disposed within case (32). As is clear from FIGs. 3 and 4, the force-feedback unit is *forward* of the skin traction mechanism, which is disposed *outside* of the housing or case (32). The skin traction mechanism resides within its own special casing (127).

Regarding point no. 2, in Cunningham, the end effector does not pass through the "pseudo skin" for any reason. The end effector (catheter needle assembly (47)) never passes through belt (108).

Regarding point no. 3, in Cunningham, the end effector does not reversibly couple to the force feedback mechanism. In fact, the end effector —catheter needle assembly (47)— is not even in contact with the force-feedback assembly (54). In this prior-art device, it is shaft (44) that is coupled to force-feedback assembly (54). Catheter needle assembly 47 is received by shaft (44). Then, the combined shaft/catheter-needle assembly is collectively manipulated.

In this regard, it is interesting to note that to initialize the device disclosed in Cunningham, catheter needle assembly (47) is inserted into shaft (44). Then, to actually perform a vascular access simulation, the combined shaft/catheter needle assembly is manipulated. So, the catheter needle assembly is not inserted into or coupled to anything as part of the simulation, itself. The simulation begins *after* the needle-catheter is already inserted into shaft (44). As a consequence, during a simulation, the catheter needle assembly (47) never decouples from shaft (44).

Since Cunningham does not disclose or suggest what is recited in amended claim 12, that claim is allowable the reference. Claims 13 through 19 are allowable based on their dependence on claim 1. Furthermore, the recitation of additional patentable features in these claims provides a secondary basis for their patentability. In view of the foregoing, applicants request that the rejection of claims 12-19 be withdrawn.

Rejection of Claim 20
under 35 U.S.C. 102
Over Cunningham

Claim 20 recites an apparatus comprising:

> an end effector;
> a housing, wherein said housing has an opening;
> pseudo skin, wherein said pseudo skin covers said opening in said housing; and
> a receiver for receiving said end effector, wherein said receiver is disposed in said housing.

Cunningham does not disclose or suggest what is recited in amended claim 20.

In Cunningham, the "pseudo skin," which would be belt (108) [to the extent that a pseudo skin is disclosed in this reference at all], does NOT substantially cover an opening in the housing (that contains the receiver). As previously noted, the pseudo skin (belt 108) is disposed on a device that is separate from the housing.

Amended claim 20 is allowable over Cunningham since that reference does not disclose or suggest the subject matter that is recited in that claim. Claims 21 through 28 are allowable based on their dependence on amended claim 20. Furthermore, the recitation of additional patentable features in these claims provides a secondary basis for their patentability. In view of the foregoing, applicants request that the rejection of claims 20-28 be withdrawn.

The secondary references disclosed by the Office, whether taken alone or in combination with Cunningham, do not provide any disclosure that would serve as a basis for rejecting the pending claims.

Conclusion

It is believed that claims 1-6, 8, and 10-28 now presented for examination are allowable over the art of record. A notice to that effect is solicited.

If there are remaining issues, the applicants respectfully request that Examiner telephone the applicants' attorney at 732-578-0103 x12 so that those issues can be resolved as quickly as possible.

Respectfully
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